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July 2, 1997

Barbara M. McGarey, J.D.
Deputy Director
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard
Suite 325
Rockville, Maryland 20852

Re: Petition of CellPro, Inc.

Dear Ms. McGarey:

Pursuant to the schedule established by Dr. Baldwin's letter of May 27, 1997, I am submitting herewith a Response in support of the petition of CellPro, Inc. for issuance of a license under the Bayh-Dole Act to certain patents that resulted from federally funded research at Johns Hopkins University.

Hopkins and its licensees have opposed the granting of the petition primarily on the basis of two arguments: (1) that there is no public health need that would be served by the grant of the requested license and (2) that the grant of the requested license would undermine rather than further the policies that underlie the Act. In its Response, CellPro addresses these arguments and shows that neither can withstand analysis.

The public health arguments advanced by Hopkins and its licensees are addressed in Part I of CellPro's Response. As discussed in more detail there:

- CellPro's CEPRATE System is the only cell separation product approved in this country for treatment of breast cancer, multiple myeloma, and lymphoma. Contrary to the representations of Hopkins and its licensees, there is no ready alternative: Treatment with the unapproved Baxter product can only occur in limited circumstances under the specific protocols of ongoing clinical trials. Even if Baxter's PMA should be approved by the FDA by the end of the year -- an event that would trigger the mandatory withdrawal from the market of the CellPro system under the terms of the injunction being sought -- that approval would only be granted for the Isolex 300SA, a product that is obsolescent if not obsolete. Far fewer treatments would be used with that product than

would be the case if CellPro is granted a license, with the consequence of far more patient suffering or death.

- Baxter's public commitment to substitute its newer Isolex 300i product for existing CellPro stem cell separation systems in ongoing clinical trials involving leukemia, multiple sclerosis, and other diseases on the same terms as are being provided by CellPro has only the appearance of mitigating the inevitable effects of the injunction being sought.

    - Even were the Baxter product an available substitute for a particular trial, it would take from six months to two years to switch from one system to the other. Unfortunately, many victims of leukemia and other diseases whose only hope for survival lies in these clinical trials will not survive that long.

    - For at least some clinical trials -- including trials involving treatment of children with leukemia -- Baxter has no equivalent product and simply would not be able to provide a substitute for the CellPro system.

    - The recent transaction announced by Baxter under which its research and development relating to stem cell therapies would be transferred to a joint venture 80 percent owned by VIMRX casts further doubt on the ability of Hopkins and its licensees to fill the void that would be created by the injunction they seek against CellPro. There is simply no basis to believe that the major research and development effort planned by CellPro in this area will be provided by the new VIMRX entity.

The Bayh-Dole policy arguments raised by Hopkins and its licensees are addressed in Part II of CellPro's Response. Briefly:

- Hopkins' entire public policy argument is based on the proposition that CellPro is seeking a license "on forced terms it would never have obtained through voluntary negotiation with the patent holder." Of course, that is not what CellPro is seeking. The Bayh-Dole Act requires that any government granted license be on reasonable terms and that is all CellPro has ever asked.

- Bayh-Dole was enacted in an effort to encourage commercial development of the fruits of government funded research. The purpose behind the law would be frustrated, not furthered, were a government grantee to use patents that resulted from its government funded research to block the fruits of other government funded research. This is in effect what Hopkins and its licensees are trying to do with patents they claim cover all stem cell products, and their efforts to block the fruits of later government funded research is particularly unjustified given that it was the effort of the second government grantee that paved the way for commercialization of stem cell transplantation.

- The small business preference embodied in Bayh-Dole was intended to provide the benefits that come from the innovative activities of small start-up companies such as CellPro. Under the law, CellPro should have been offered the 5.5% exclusive license Baxter received from Becton Dickinson in 1990. The Department can and should properly take this fact into account in acting on CellPro's petition to prevent Hopkins and its licensees from benefitting from their violation of an important provision of the Bayh-Dole Act.

At your request, CellPro has addressed in Part III of its Response the claim by Hopkins and its licensees that the Department lacks jurisdiction to issue the requested license. As discussed there, the claim that the patents at issue were not the fruits of government funded research is entirely without merit, and the implicit threat in the Hopkins submissions to engage in frivolous litigation on that issue and the equally unjustifiable threat to tie the Department up in lengthy administrative proceedings should be ignored.

In this letter and the accompanying Response, we have attempted to avoid the kind of invective and rhetoric that has characterized the submissions by Hopkins and its licensees. I would be remiss, however, if I did not take exception to the repeated claims that CellPro has been found by a jury to be a "willful infringer" which has "stolen" Hopkins' intellectual property.

In fact, the only jury to hear the infringement issues in the patent litigation found that the Hopkins patents were invalid and not infringed by the CellPro technology. CellPro did continue to make that technology available in the form of support for critically important clinical trials and patient treatments even after the district court set aside the jury's verdict. In that sense, perhaps CellPro can be regarded as a "willful infringer," but even now Hopkins and its licensees claim that they are not seeking to deprive patients from using the CellPro technology pending FDA approval of a Baxter product.

Nor has CellPro ever proposed to use anyone's intellectual property without payment. CellPro's entire business is based on licenses issued on technology developed under the provisions of the Bayh-Dole Act at the Fred Hutchinson Cancer Research Center. It is true that CellPro has resisted the claims of Hopkins and its licensees that its technology infringes any valid patent assigned to Hopkins. This, of course, is a right guaranteed by the patent laws to help guard against the existence of improper monopolies. However, as you know, CellPro has also made clear that if its belief that the Hopkins patents are neither valid nor infringed by the CellPro technology is not upheld in court, CellPro is prepared to pay more than Baxter has demanded from others for a license to the Hopkins patents. It is perhaps understandable that Baxter does not wish to subject its patent claims to an appeal to the Federal Circuit. But at the same time, Baxter cannot claim that CellPro's offer which would result in Baxter's receipt of $1.5 million plus an 80 percent mark-up over the 5.5% royalty it is required to pay on its Becton Dickinson license constitutes the "theft" of intellectual property.

CellPro is committed to attempting to find a solution to its dispute with Hopkins and its licensees that will avoid the necessity of Department action on its petition. It will continue its efforts towards that end between now and the August 2, 1997, date upon which the applicable regulations require the Department to act on CellPro's petition. In the event, however, that those efforts are unsuccessful, CellPro requests that the Department initiate march-in proceedings pursuant to 37 C.F.R. § 401.6(c).

Moreover, CellPro submits that there is no material factual dispute that would need to be resolved before the license issues. Even on the facts as proffered by Hopkins and its licensees, there is a more than adequate basis for the Department to find a public health need and to exercise its Bayh-Dole march in rights. But in the event the Department should conclude that factual disputes preclude issuance of an immediate license, CellPro requests that it order the most expedited proceeding possible to resolve such issues. Only by such action can there be assurance of a timely resolution of a matter that may literally be one of life and death for affected patients.

Thank you again for your consideration of CellPro's petition. Please let me know if you have any questions about the enclosed or if I may otherwise be of assistance.

Very truly yours,

Gary D. Wilson

cc: Donald R. Ware
Frederick G. Savage
Robert B. Lanman